

REMARKS

Reexamination of the application in light of the amendment and remarks herein set forth is respectfully requested.

Applicant has inserted the heading "Parent Case Text" prior to the claims. The text suggested by the Examiner has been inserted under this new heading. The insertion of the heading and text should be sufficient to permit the Examiner's objection to the withdrawn.

REJECTIONS UNDER 35 U.S.C. § 102

Claims 1-3, 5-6, 8, 10-11, and 14 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Woo et al., ("Woo") (U.S. Patent No. 5,994,109), and alternatively, as being anticipated by Smith et al. ("Smith") (WO 93/18759). Applicant respectfully traverses and requests withdrawal of the rejection based on the Declaration submitted herewith.

The Examiner states the transporter in Woo comprising a spacer (such as a (gly₁₋₆-ser₁₋₆)₃₋₂₀ repeat spacer) connecting a binding molecule and a nuclear ligand anticipates the instant invention of a hinge region of neutral amino acids connecting a polymeric chain of basic amino acid residues and a nuclear localization signal.

Applicant observes that the filing date of the 5,994,109 patent is June 3, 1995 whereas the filing date of the original Gopal patent is May 11, 1994. Thus, to be a reference under § 102(e) as "prior art" the filing date of a parent application must be used. The earliest date that could be asserted would be held by application 07/855,389, filed March 20, 1992. However, in order to carry back the § 102(e) critical date of the reference, the parent application must support the invention claimed as required by 35 U.S.C. § 112, first paragraph. (M.P.E.P. § 2136.03 IV). However, Applicant observes that the specification of the 07/855,389 application was objected to under 35 U.S.C. § 112, first paragraph.

Examiner Hodges states, in part:

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to use the invention, i.e., failing to provide an enabling disclosure. Applicants claim a DNA transporter system useful for transporting DNA into eucaryotic cells. Applicants have provided no working examples of actual DNA transport. Applicants have provided no protocols nor has reference been made to any protocols for using the instantly claimed DNA transporter system or DNA binding complexes in a method to transport DNA into cells. Without such examples and guidance, one of ordinary skill of the art would need to create and try numerous protocols of DNA transport in order to use the instantly claimed DNA transporter system. Such activity amounts to extensive experimentation of an unpredictable nature. There are numerous parameters for which no guidance is given. For example, the nature and concentration of salts cofactors, the temperature, the incubation time, cell or subject preparation, DNA loading onto the DNA binding complexes would each require separate testing and optimization. Any one of these or numerous other factors alone would require undue experimentation in its determination and practice due to an extensive and unpredictability of the effect of these factors on DNA transport. (See 07/855,389 application file history, paper 9, pp. 10-11).

In response, without any attempt to traverse, Woo allowed application 07/855,389 to go abandoned after filing a continuation-in-part, application 08/167,641, on December 14, 1993. The 08/167,641 application adds and addresses the 35 U.S.C. § 112, first paragraph support required by Examiner Hodges in columns 76 through 94. Portions of claims filed in application

08/167,641 were divided out into application 08/460,890, which issued as the cited reference U.S. Patent No. 5,994,109.

Thus the December 14, 1993 filing date of application 08/167,641 is apparently the earliest § 102(e) critical date possible -- not that of application 07/855,389. A reference must be enabling to act as prior art and "if a patent could not theoretically have issued the day the application was filed, it is not entitled to be used against another as 'secret prior art'." (*In re Wertheim*, 646 F.2d 527, 537, 209 USPQ 554, 564 (CCPA 1981). It should also be noted that the (gly₁₋₆-ser₁₋₆)₃₋₂₀ formula relied upon in the Examiner's rejection is not described in the 07/855,389 application.

Alternatively, Examiner cites the Smith reference WO 93/18759, filed March 19, 1993. The Smith reference suffers from the same flawed specification as the Woo reference. However, to expedite prosecution of the instant application, Applicant will assume the September 30, 1993 publication date of the Smith reference is the critical date. (MPEP § 2136.03 II 2).

Applicant submits herewith a Declaration under 37 C.F.R. § 1.131 by the inventor that states actual reduction to practice of the Gopal invention was performed before the Woo or Smith reference dates. Applicant submits that the references are thus removed and may not be relied upon by the Examiner. Accordingly, the rejection under 35 U.S.C. § 102(e) of claims 1-3, 5-6, 8, 10-11, and 14 should be withdrawn.

REJECTIONS UNDER 35 U.S.C. § 103

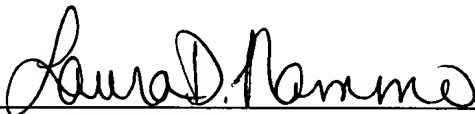
Claims 1-11 and 14 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over either Woo (U.S. Patent No. 5,994,109) or Smith (WO 93/18759) in view of Short (U.S. Patent No. 5,589,392). Claims 1-3, 5-6, 8, and 10-14 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over either Woo (U.S. Patent No. 5,994,109) or Smith (WO 93/18759) in view of

Gorman (U.S. Patent No. 5,024,939). Specifically, the Examiner states the (gly₁₋₆-ser₁₋₆)₃₋₂₀ spacer taught by Woo reads on the hinge region of neutral amino acids taught by Gopal in the instant application.

For the reasons stated above, Applicant will use the September 30, 1993 publication date of the Smith reference as the critical date. Applicant submits that the attached Declaration removes the Woo (U.S. Patent No. 5,994,109) and Smith (WO 93/18759) references. Since neither the Short reference nor the Gorman reference teaches the invention of the instant application, the rejection under 35 U.S.C. § 103(a) of the claims should be withdrawn.

CONCLUSION

Applicant respectfully submits that the claims now stand ready and in condition for allowance. Early consideration of the above amendments and remarks and of the Declaration attached is respectfully requested.

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